TO: Examiner Shengiun Wang - United States Patent and Trademark Office

Fax No. 571-273-8300 Phone No. 571-272-0632

FROM: Linda S. Jernigan **(Typed or printed name of person signing Certificate)**

Fax No. 513-622-3300 Phone No. 513-622-2811

Application No.: 09/291,227

Inventor(s): Michael G. Hayek

Filed: April 13, 1999

Docket No.: P-114

Confirmation No.: 1828

FACSIMILE TRANSMITTAL SHEET AND

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on May 30, 2006, to the above-identified facsimile number.

Linda S. Jernigan (Signature)

Listed below are the item(s) being submitted with this Certificate of Transmission:**

1) Fee Transmittal: 1 pg. – orig. w/copy if applicable

2) Appeal Brief W/Claims Appendix, Evidence Appendix and Related Proceedings Appendix - 16 pgs.

Number of Pages Including this Page: 19 pgs.

Comments:

**Note: Each paper must have its own certificate of transmission, OR this certificate must identify each submitted paper.

(FAX-USPTO.doc Revised 11/18/2005)

FEE TRANSMITTAL
for FY 2005

Patent fees are subject to annual revision.
Effective December 8, 2004

TOTAL AMOUNT OF PAYMENT ($)2660

Complete if Known	
Application Number	09/291,227
Confirmation Number	1828
Filing Date	April 13, 1999
First Named Inventor	Michael G. Hayek
Examiner Name	Shengjun Wang
Art Unit	1617
Attorney Docket No.	P-114

METHOD OF PAYMENT

1. [X] The Director is hereby authorized to charge indicated fees submitted on this form, credit any over payments, and charge any additional fee(s) during the pendency of this application to:

Deposit Account Number: 16-2480
Deposit Account Name: The Procter & Gamble Company

FEE CALCULATION

2. BASIC FILING FEE – Large Entity

Application Type	FILING FEE	SEARCH FEE	EXAMINATION FEE	Fee Paid
Utility	($300)	($500)	($200)	(Total = $1000) []
Design	($200)	($100)	($130)	(Total = $430) []
Reissue	($300)	($500)	($600)	(Total = $1400) []
Provisional filing fee				(Total = $200) []

3. APPLICATION SIZE FEE:
Sheets of Spec and Drawings []
($250 for each 50 sheets in excess of 100, except for sequence and program listings)
SUBTOTAL (2)+(3) ($)[]

4. EXTRA CLAIM FEES FOR UTILITY AND REISSUE:

	Extra Claims		Fee from Below		Fee Paid
Total Claims	[] - 20** =	[] x	[]	=	[]
Independent Claims	[] - 3** =	[] x	[]	=	[]
Multiple Dependent claims:			[]	=	[]

** or number previously paid, if greater; For Reissues, see below

Fee Description
Claims in excess of 20 ($50 per claim)
Independent claims in excess of 3 ($200 per claim)
Multiple dependent claim, if not paid ($360)
**Reissue: each independent claim over 3 and more than in the original patent ($200 per claim)
**Reissue claims: each claim over 20 and more than original patent ($50 per claim)

SUBTOTAL (4) ($)[]

FEE CALCULATION (continued)

5. ADDITIONAL FEES

Fee Description		Fee Paid
Extension for reply within 1st month	($120)	[]
Extension for reply within 2nd month	($450)	[]
Extension for reply within 3rd month	($1,020)	[]
Extension for reply within 4th month	($1,590)	[]
Extension for reply within 5th month	($2,160)	[x]
Information Disclosure Statement fee	($180)	[]
37 CFR 1.16(e) Late Oath/Declaration (nonprovisional)	($130)	[]
37 CFR 1.17 (q) Missing Parts (provisional)	($50)	[]
Non-English specification	($130)	[]
Notice of Appeal	($500)	[]
Filing a brief in support of an appeal	($500)	[x]
Request for oral hearing	($1,000)	[]
Acceptance of unintentionally delayed claim for priority under 35 U.S.C. 119, 120, 121, or 365 (a) or (c)	($1,370)	[]
Other: _____		[]

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SUBTOTAL(5) ($) [2660]

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	Kelly McDow-Dunham	Registration No. (Attorney/Agent)	43,787	Telephone	(513) 622-0159
Signature				Date	5-30-06

This collection of information is required by 37 CFR 1.17. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P. O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Feetrans.doc (Revised for P&G use 01/24/2005)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	09/291,227
Applicant(s)	:	Michael G. Hayek
Filed	:	April 13, 1999
Title	:	LUTEIN-CONTAINING SUPPLEMENT AND PROCESS FOR ENHANCING IMMUNE RESPONSE IN ANIMALS
TC/A.U.	:	1617
Examiner	:	Shengjun Wang
Conf. No.	:	1823
Docket No.	:	P-114
Customer No.	:	27752

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

This Brief is filed pursuant to the appeal from the Final Office Action dated March 11, 2005. A timely Notice of Appeal was filed on August 12, 2005.

REAL PARTY IN INTEREST

The real party in interest is The Iams Company, having a place of business at Dayton, Ohio. The Iams Company is an affiliated company of The Procter & Gamble Company, having a place of business at Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

STATUS OF CLAIMS

Claims 1 and 3 – 8 are rejected.

Claims 1 and 3 – 8 are appealed.

Claims 2 and 19 – 16 have been cancelled.

A complete copy of the appealed claims is set forth in the Claims Appendix attached herein.

STATUS OF AMENDMENTS

No amendment subsequent to the Notice of Appeal has been filed.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to processes for enhancement of immune response in a companion animal, wherein the companion animal is a dog or a cat.

In particular, in accordance with this invention, a dog or cat in need of enhancement of immune response (*i.e.*, treatment) is fed a diet containing from about 1 to about 50 mg per day of lutein for a time sufficient for the lutein to be absorbed by the dog or cat.

Lutein is a carotenoid. Carotenoids are naturally-occurring plant pigments that are absorbed in varying degrees by different species of animal (human or otherwise). Some carotenoids, such as *beta*-carotene, have been extensively studied in various species of animal. At the time of filing, it is believed that few studies had been conducted with regard to the physiologic function of lutein. See specification, page 1, first paragraph, and paragraph bridging pages 1 and 2.

Through a series of extensive studies leading to this invention, dietary lutein absorption specifically in these species has been observed to provide sufficient lutein to be absorbed by the dog or cat and supplied to the blood leukocytes and neutrophils in the animal. The present inventors discovered that dietary lutein significantly enhances cell-mediated immune response specifically in the dog and the cat. See specification, page 2, second full paragraph and supporting experimental procedures and results, pages 4 – 23.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. The Examiner has rejected Claims 1 and 3 – 8 under 35 U.S.C. § 103(a) in view of Ito *et al.*, U.S. Patent No. 5,937,790 (herein referred to as "Ito"). The rejection is flawed and arguments against this flawed rejection are presented for Appeal.

2. The Examiner has rejected Claims 1 and 3 – 8 under 35 U.S.C. § 103(a) in view of the aforementioned Ito reference, in combination with Jyonouchi *et al.*, "Immunomodulating Actions of Carotenoids: Enhancement of *In Vivo* and *In Vitro* Antibody Production to T-Dependent Antigens," Nutrition and Cancer, Vol. 21, No. 1, pp. 47 – 58 (1994) (herein referred to as "Jyonouchi"), Anon (IDS, March 22, 2002) (herein referred to as "Anon"), Krinsky, "Effects of Carotenoids in Cellular and Animal Systems," Am. J. Clin. Nutr., Vol. 53, 238S – 46S (1991) (herein referred to as "Krinsky") and CRC Handbook of Toxicology. The rejection is flawed and arguments against this flawed rejection are presented for Appeal.

ARGUMENTS

The separate rejections of Claims 1 and 3 – 8 based on Ito and based on Ito in combination with Jyonouchi, Anon, Krinsky and CRC Handbook of Toxicology are both flawed and should be reversed.

1. *The Rejection Under 35 U.S.C. § 103(a) in view of Ito*

The Examiner has rejected Claims 1 and 3 – 8 under 35 U.S.C. § 103(a) in view of Ito *et al.*, U.S. Patent No. 5,937,790 (herein referred to as "Ito").

Ito relates to compositions containing L-ascorbic acid-2-phosphoric acid or L-ascorbic acid-2-glucoside as active components for the alleviation of stress in useful economic animals. Ito states that "when L-ascorbic acid-2-monophosphate, an L-ascorbic acid-2-

glucoside or a salt thereof is used as an L-ascorbic acid derivative, the increase of stress plasma LDH, MDH and AspAT and stress proteins in blood can be advantageously suppressed." See Ito, Column 6, lines 61 – 65. These agents are attributed by Ito as useful for avoidance of serious disease or other conditions associated with stress, and therefore an immune function is accredited to these L-ascorbic acid-2-phosphoric acid or L-ascorbic acid-2-glucoside agents. See Ito, Column 4, lines 9 – 12.

The Examiner places flawed emphasis on the disclosure of any of a variety of anti-oxidant substances in combination with the L-ascorbic acid-2-phosphoric acid or L-ascorbic acid-2-glucoside anti-stress agents. Ito states that unfortunately these L-ascorbic acid-2-phosphoric acid and L-ascorbic acid-2-glucoside agents are readily susceptible to oxidation, and thus decomposition, and are swiftly deactivated after being added to feed.

Ito therefore discloses combination of the L-ascorbic acid-2-phosphoric acid or L-ascorbic acid-2-glucoside agents with any of a variety of antioxidant substances selected from carotene, astaxanthin, lutein, dl-alpha-tocopheryl acetate, alpha-tocopherol, SOD, glutathione, and catechins order to prevent or inhibit oxidation of the active thereby enhancing the efficacy of the L-ascorbic acid-2-phosphoric acid or L-ascorbic acid-2-glucoside as anti-stress agents.

Ito discloses that lutein may optionally be selected among a variety of antioxidants (carotene, astaxanthin, lutein dl-alpha-tocopheryl acetate, alpha-tocopherol, SOD, glutathione and catechins) *in order to intensify the suppression of* animal stress plasma LDH, MDH and AspAT and stress proteins, since these antioxidants preserve the structural integrity of the ascorbic acid anti-stress agents. Ito does not expressly or impliedly suggest that any of these antioxidants actually contribute to the anti-stress action of the composition in any animal (whether stressed or not), other than for preservation of the ascorbic acid anti-stress agent which is responsible for this action. See e.g., Column 1, lines 50 – 63.

Moreover, Ito does not expressly or impliedly attribute any anti-stress or immune function to any animal feed that does not contain the L-ascorbic acid-2-phosphoric acid

or L-ascorbic acid-2-glucoside agents. Nowhere does Ito teach or even suggest that any of the antioxidants alone, and lutein in particular, are useful for the enhancement of immunity or for any purpose other than preserving the structural integrity of the L-ascorbic acid-2-phosphoric acid or L-ascorbic acid-2-glucoside anti-stress agents.

The Examiner has stated that Ito administers compositions containing carotene and lutein. The Examiner has further drawn from Column 1, lines 23 – 25, which states that the anti-stress agent of Ito can prevent the stress reaction of animals and inhibit various disorders accompanying the stress, such as loss in body weight and a reduction in immunity. *However, it is the L-ascorbic acid-2-phosphoric acid or L-ascorbic acid-2-glucoside anti-stress agents to which Ito attributes these functions, not any of the antioxidants further disclosed by Ito.*

There would therefore have been no reasonable expectation that the same or similar functions could be achieved by utilizing any of the antioxidant components disclosed by Ito, and in particular selecting specifically lutein, in lieu of the L-ascorbic acid-2-phosphoric acid or L-ascorbic acid-2-glucoside anti-stress agents described by Ito. Ito merely discloses the antioxidant compounds for use as a protective agent for the active L-ascorbic acid-2-phosphoric acid or L-ascorbic acid-2-glucoside anti-stress agents.

Moreover, the disclosure of Ito only relates to animals which are stressed. For example, Example 1 of Ito tests swines which are transferred to a separate swine house to induce stress. Ito states that "[i]t was confirmed from past experience that this transfer and change of group formation imposes stress on swine and causes problems such as a reduction in incremental body weight." See Ito, Column 9, lines 52 – 61. As yet another example, Example 2 of Ito tests cattle in which the "bulls in the test segment and the control segment were transported on land over a distance of 567 km by trucks at the initiation of the test . . ." See Ito, Column 12, lines 15 – 18. As yet a further example, Example 3 tests beagles which are "performed by breeding the beagles in an open stock-rasing house installed in the fields in a high temperature season of summer from August 1 to 30 in 1995. The temperature of the raising house was not particularly controlled." See Ito, Column 12, lines 61 – 65. No other mammalian tests are described.

This disclosure relating only to stressed animals is important because Ito relates the described compositions to prevention of the stress reaction and inhibition of various disorders accompanying the stress, such as a loss in body weight and a reduction in immunity. See Column 1, lines 23 – 25. Nowhere does Ito describe actual *enhancement of immunity* (which is specifically recited in Appellant's claims) by any component (even the ascorbic acid derivative anti-stress agents) in either healthy or stressed animals. *Importantly, the Examiner is assuming that alteration of measured stress protein results in changes in immune response, however, this is not demonstrated by Ito. Moreover, the Examiner is equating inhibition of reduction in immunity with enhancement of immunity. This is not demonstrated by Ito.*

Even further, Ito fails to describe or even suggest treatment of healthy, unstressed animals. Again, Ito is merely focused on combating the effects of a stress condition. Applicant has demonstrated the effects of enhanced immunity through administration of the compositions described in the present specification, which effects were discovered based on use of healthy animals under non-stress (or, ordinary) conditions.

The Examiner has therefore relied on a disclosure of use of an ascorbic acid derivative as an anti-stress agent, and has improperly translated this to suggestion of lutein for enhancement of immune response. The rationale is flawed and should not be supported by the Board.

Ito fails to teach or even suggest enhancement of immunity in a cat or dog through administration of lutein. Respectfully, it is requested that the Board reverses the rejection based on Ito.

2. ***The Rejection Under 35 U.S.C. § 103(a) in View of Ito***

The Examiner has rejected Claims 1 and 3 – 8 under 35 U.S.C. § 103(a) in view of the aforementioned Ito reference, in combination with Jyonouchi *et al.*, "Immunomodulating Actions of Carotenoids: Enhancement of *In Vivo* and *In Vitro* Antibody Production to T-

Dependent Antigens," Nutrition and Cancer, Vol. 21, No. 1, pp. 47 – 58 (1994) (herein referred to as "Jyonouchi"), Anon (IDS, March 22, 2002) (herein referred to as "Anon"), Krinsky, "Effects of Carotenoids in Cellular and Animal Systems," Am. J. Clin. Nutr., Vol. 53, 238S – 46S (1991) (herein referred to as "Krinsky") and CRC Handbook of Toxicology. The rejection is flawed and arguments against this flawed rejection are presented for Appeal.

The deficiencies of Ito are argued as above.

One of the secondary references, Jyonouchi, teaches that the intraperitoneal injection of lutein in mice in specific amounts may enhance humoral immune response in mice. The reference fails to teach or suggest any injection of lutein in any animal other than mice, and fails to teach or suggest oral administration of lutein in any animal for any purpose.

In order to establish obviousness, the Examiner must consider whether the claimed invention *as a whole* would have been obvious in view of the cited references. Consistent with this requirement, distilling an invention down to the "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter as a whole. See MPEP 2141.02. As such, each and every element of the claimed invention must be considered when determining whether a collection of references would have suggested the invention as a whole.

Respectfully, the Examiner is improperly disregarding the claimed invention as a whole. A reading of the independent Claim 1 reveals that the claimed invention recites processes for enhancing immune response of a dog or cat utilizing a diet which contains a very specific amount of lutein. In particular, the claims require the diet to contain from about 1 to about 50 mg/day of lutein. This is a claim limitation that should not be ignored while considering patentability of the present claims.

Indeed, reading the claim as a whole, including all limitations, is important in view of the cited combination of references. A combination of Ito with Jyonouchi fails to arrive at the present invention for several reasons. First, as supported by the declaration of Dr. Michael Hayek (previously submitted and set forth at Appendix A), one of ordinary skill in the art would have failed to infer from the combination of references that lutein would be absorbed at effective levels following oral administration so as to have the claimed effect on the immune system and immune response in a cat or a dog. Indeed, since Jyonouchi only shows humoral immune response in mice by intraperitoneal injection, and Ito merely states that an antioxidant chosen from a laundry list of possibilities can be fed orally to protect against degradation of the ascorbic acid derivative anti-stress agent, one of ordinary skill would have failed to deduce that immune response could be enhanced in dogs or cats through oral administration in feed.

Even further, and even assuming *arguendo* that one would be led to enhance immune response in dogs or cats through oral administration of lutein, one of ordinary skill would have no understanding or basis for selecting the appropriate, effective amount of lutein in the diet. Indeed, each independent claim of the invention as presently claimed requires from about 1 to about 50 mg/day of lutein in the diet in order to effect the recited functional response, which is not taught or even suggested in either Ito or Jyonouchi. Moreover, the remaining secondary references (Anon, Krinsky, and CRC Handbook of Toxicology) fail to fill this important gap. Indeed, throughout prosecution of the present invention, the Examiner was not successful in any showing that each and every element of the claimed invention was taught or suggested through the combination of references.

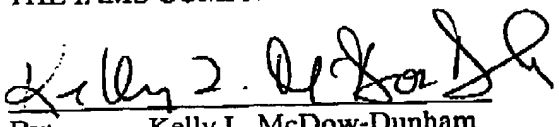
Accordingly, since the references cited by the Examiner fail to teach each and every element of the claimed invention, the Examiner has failed to establish obviousness. It is therefore respectfully requested that the Board reverse the rejection.

SUMMARY

In view of all of the above, it is respectfully submitted that the separate rejections of Claims 1 and 3 – 8 in view of Ito and Ito in combination with Jyonouchi, Anon, Krinsky and CRC Handbook of Toxicology are flawed. Appellant therefore requests that the

Board reverse the rejections of the Examiner such that the present inventive claims may proceed to issue.

Respectfully submitted,
THE IAMS COMPANY



By: Kelly L. McDow-Dunham
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Date: Rev. – May 30, 2006
Orig. – February 23, 2006
Customer No. 27,752

Application No. 09/291,227
Attorney Docket No. P-114
Non-Compliant Appeal Brief dated May 30, 2006
Customer No. 27,752

CLAIMS APPENDIX

1. (Appealed) A process for enhancing immune response of a companion animal consisting of a dog or cat, said process comprising the step of feeding said animal in need of such treatment a diet containing an effective immune enhancing amount of lutein, wherein the diet contains from about 1 to about 50 mg/day of lutein for a time sufficient for said lutein to be absorbed by said animal.

2. (Canceled).

3. (Appealed) A process as claimed in claim 1 in which said diet includes from about 2 to about 315 mg lutein per kg of diet.

4. (Appealed) A process as claimed in claim 1 wherein said companion animal is a dog.

5. (Appealed) A process as claimed in claim 4 in which said diet includes from about 5 to about 20 mg/day of lutein.

6. (Appealed) A process as claimed in claim 1 wherein said companion animal is a cat.

7. (Appealed) A process as claimed in claim 6 in which said diet includes from about 5 to about 10 mg/day of lutein.

8. (Appealed) A process as claimed in claim 1 in which said diet comprises about 20 to 40% crude protein, about 4 to 30% fat, and about 4 to 20% total dietary fiber.

9. (Canceled).

10. (Canceled).

11. (Canceled).

12. (Canceled).

13. (Canceled).

14. (Canceled).

15. (Canceled).

16. (Canceled).

Application No. 09/291,227
Attorney Docket No. P-114
Non-Compliant Appeal Brief dated May 30, 2006
Customer No. 27,752

EVIDENCE APPENDIX

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EVIDENCE APPENDIX

S/N 09/291,227

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Michael Griffin Hayek	Examiner: Shengjun Wang
Serial No.:	09/291,227	Group Art Unit: 1617
Filed:	April 13, 1999	Docket: 1448.019US1
Title:	LUTEIN - CONTAINING SUPPLEMENT AND PROCESS FOR ENHANCING IMMUNE RESPONSE IN ANIMALS	

DECLARATION OF MICHAEL GRIFFIN HAYEK UNDER 37 C.F.R. § 1.132

I, Michael Griffin Hayek, state and declare as follows:

1. I am Director, Strategic Research, with The Iams Company, Lewisburg, Ohio. My principal job responsibility is as a researcher investigating animal nutritional products and methods for improving animal health.

2. I have been continuously employed by The Iams Company since April 1, 1995. Prior to working at The Iams Company I was a Postdoctoral Fellow at the U.S.D.A. Center of Aging at Tufts University from May 1991 until May 1995. I have conducted considerable research in areas such as nutrition and animal health.

3. I have a Ph.D. degree in Interdisciplinary Nutrition from the University of Kentucky, Lexington, Kentucky, 1991; and a Masters of Science degree in Animal Science from the University of Kentucky, Lexington, Kentucky, 1987. I have published about 31 papers in peer reviewed journals concerned with nutritional biochemistry. I have been named as an inventor or co-inventor on about 7 U.S. Patents in the field of Companion Animal Nutrition.

4. I am the named sole inventor on the above patent application which claims diet-based processes for:

enhancing the immune response of a companion animal, such as a dog or cat (Claims 1, 3, 4, 5, 6, 7, and 8);

increasing the lutein concentration in the circulating blood of a companion animal(Claim 9);

increasing the immunoglobin concentration in a companion animal(Claim 10); and

increasing the lymphocyte cells in a companion animal(Claim 11).

These processes involve feeding the companion animal in need of such treatment a diet containing an effective amount of a lutein supplement. The diets can contain, for example, from about 1 to about 50 mg/day of lutein, and are orally administered for a time sufficient for the lutein to be absorbed by the animal.

5. I have reviewed the official action dated April 23, 2002, and the documents: Jyonouchi et al., and Ito et al. For the reasons below I believe the subject matter of the pending claims, that oral administration of lutein and its effect on the immune response, is not suggested to one skilled in the art by the cited documents because, for example:

a) administration of lutein in Jyonouchi is intraperitoneally and not by feeding or oral administration as in the present invention; and

b) Jyonouchi teaches local injection near the spleen and thereby creates a highly localized concentration of lutein.

Therefore, it is my opinion that a skilled artisan could not have reasonably inferred from the Jyonouchi reference that lutein would be absorbed at effective levels following oral

administration to have the claimed affect on the immune system and immune response in companion animals.

6. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any registration resulting therefrom.

Signed at Lewisburg, OH, this 28 day of 6, 2002.

Respectfully submitted,

By: Michael Griffin Hayek

Name: MICHAEL GRIFFIN HAYEK
Title: Director, Strategic Research

Application No. 09/291,227
Attorney Docket No. P-114
Customer No. 27,752

RELATED PROCEEDINGS APPENDIX

None